IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

In re: Genentech, Inc., Herceptin (Trastuzumab) Marketing and Sales Practices Litigation	)	MDL Docket No. 16-MD-2700
	)	Document Relates to: **All Cases**

PLAINTIFFS' RESPONSE TO DEFENDANT'S MOTION FOR PROTECTIVE ORDER

To paraphrase Yogi Berra, Genentech's Motion is like "déjà vu all over again." In negotiating the Protective Order, Genentech tried to convince Plaintiffs' counsel it was entitled to an Attorneys' Eyes Only designation for its documents. Plaintiffs disagreed. Genentech then tried to convince this Court such protection was essential, arguing that disclosure to even a small subset of Plaintiffs' representatives presented a danger that its trade secrets would be disclosed to its competitors. This argument was rejected and Genentech's request overruled. Genentech appealed that decision to the District Court, where its appeal was denied.

Despite this denial, Genentech has designated over 97% of the pages in its productions so far as "Attorneys' Eyes Only."[1] As its final flourish, Genentech then advised Plaintiffs that if they did not honor this designation—found nowhere in the Protective Order, they would be sued.[2]

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[1] Genentech has produced 6,873 pages in discovery as of July 29, 2016. Genentech has stamped 6,706 pages as "attorneys' eyes only." Many of the 167 pages Genentech produced without an "attorneys' eyes only" designation are documents that are publicly available, *i.e.,* copies of labels, physician's inserts, and Herceptin packages.

[2] Letter from O'Connor to Keglovits at 9 (July 19, 2016) (MDL Doc. #64-8 filed July 28, 2016).

For the reasons discussed ad nauseum and set forth again below, Genentech has not met the high burden for such a restrictive departure from the normal discovery rules. Plaintiffs request the Court deny Genentech's Motion for Protective Order.

BACKGROUND

Genentech has repeatedly asked the Court to depart from its standard protective order to provide for a category of documents to which access is even more restrictive than the "Highly Confidential Information" category the parties agreed upon. Each time, Genentech's argument has been premised on an unsupported assertion that Plaintiffs will not abide by the Protective Order and will instead disclose information to other individuals and entities.

This Court previously has considered whether to restrict Plaintiffs' access to documents, thereby foreclosing their attorneys' ability to discuss them with Plaintiffs, and the arguments have not changed. *See* Def.'s Motion for Protective Order (Doc. #73 in 15-cv-157) (Dec. 15, 2015); Pls.' Response to Motion for Protective Order (Doc. #78 in 15-cv-157) (Jan. 5, 2016); Transcript of Hearing (Jan. 7, 2016) (Doc. #90-3 in 15-cv-157 filed Feb. 8, 2016); Protective Order (Doc. #86 in 15-cv-157); Def.'s Obj. to Magistrate Judge's Protective Order (Doc. #90 in 15-cv-157) (Feb. 8, 2016); Pls.' Resp. to Obj. to Magistrate's Protective Order (Doc. #93 in 15-cv-157) (Feb. 22, 2016); Def.'s Reply in Support of Obj. to Magistrate Judge's Protective Order (Doc. #96 in 15-cv-157) (Mar. 14, 2016); Protective Order (MDL Doc. #43) (June 24, 2016). Genentech

provides no new argument for why an allegedly case-dispositive document cannot be discussed by Plaintiffs - who are not competitors to Genentech - and their attorneys.

While providing no new arguments, Genentech also ignored the Court's permissive option to ask for attorneys' eyes only treatment on a case-by-case basis. Genentech repeatedly raised this exact document at the Case Management Conference, and Judge Kern denied Genentech's appeal to change the Protective Order. Genentech knew this document would need to be produced. Genentech could have filed this Motion the day after the Case Management Conference. Yet a month after the Case Management Conference, Genentech had not asked the Court to designate the CMC as attorneys' eyes only. Genentech, instead, waited until after discovery requests were made, after the entire time to respond to those requests had expired, and then, without Court approval, unilaterally designated the CMC as attorneys' eyes only.

Since Genentech's Motion was filed, Genentech produced 3,854 more pages and unilaterally designated every page as attorneys' eyes only without first asking the Court for such a designation.

The standard protective order incorporates "confidential" and "highly confidential" categories and provides adequate protection to confidential information that arises in litigation. To prevent the sharing of documents among Plaintiffs' counsel and their client representatives, as Genentech seeks, inappropriately handcuffs Plaintiffs in their case development and conflicts with the open discovery process fostered and protected by the Federal Rules of Civil Procedure.

STANDARD OF REVIEW

Genentech bears the burden of demonstrating "good cause" for a more restrictive protective order. *See Littlebear v. Advanced Bionics, LLC*, No. 11-CV-418-GKF-PJC, 2012 WL 2979023, at *1 (N.D. Okla. July 20, 2012) ("The moving party bears the burden of demonstrating 'good cause' and requires a particular and specific demonstration of fact as distinguished from conclusory or stereotyped statements."). Thus, Genentech is incorrect when it attempts to shift the burden to Plaintiffs, *see* Mot. at 7 ("the burden lies with Plaintiffs..."), *id.* ("the burden on Plaintiffs...").

Genentech's cited cases also do not support its claim that the Court should, over Plaintiffs' objection, deny their ability to discuss relevant documents with their attorneys. *See Paycom Payroll, LLC v. Richison*, 758 F.3d 1198, 1202 (10th Cir. 2014) (holding a party "may" consent to an attorneys' eyes only provision in case where the parties agreed, in a consent decree, to such a provision); *CTI Servs. LLC v. Haremza*, No. 09-cv-144-GKF-TLW (N.D. Okla. May 17, 2011) (parties stipulated to an attorneys' eyes only provision); *Legates v. Oklahoma ex rel Rogers Cty. Dep't Of Human Servs.*, No. 09-CV-29-TCK-FHM, 2009 WL 3104677, at *2 (N.D. Okla. Sept. 8, 2009) (ordering parties confer on a protective order that could include an attorneys' eyes only provision). Even the two protective orders Genentech provides were *stipulated* by the parties. *See* Mot. at 6. Here, Plaintiffs have not stipulated to an attorneys' eyes only provision.

Thus, Genentech retains the burden to show that the "Highly Confidential Information" category is insufficient to protect its interests.

ARGUMENT

I. An Attorneys' Eyes Only Restriction Will Inappropriately Handcuff the Plaintiffs and Conflicts with Open Discovery Process Protected by the Federal Rules of Civil Procedure.

Genentech's proposed restriction will inappropriately and unnecessarily handcuff and complicate Plaintiffs' attorney-client communications, discovery, development of their claims, and the case proceedings. Plaintiffs' counsel should be able to discuss the relevant case information with their clients. *See* Transcript of Hearing at 36-37 (Jan. 7, 2016) (Doc. #90-3 in 15-cv-157 filed Feb. 8, 2016) ("MR. KEGLOVITS: We clearly want to be able to talk with our clients about relevant case information and so we don't believe it's right that we can't talk with any of our clients or any of their employees about highly confidential information.").

The document directly at issue in this motion is the same document Genentech cites as case-dispositive. According to Genentech, the Chemistry, Manufacturing, and Controls section of the Biologics License Application for Herceptin permits Genentech to provide less Herceptin than warranted and to misstate the concentration of Herceptin solution:

> INTERROGATORY NO. 5: Identify the specific range of variance approved by the FDA relating to the amount of Trastuzumab in each vial of Herceptin.
>
> ANSWER: Subject to and without waiving its General Objections, and pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, Genentech directs Plaintiffs to the Chemistry, Manufacturing and Controls section of its initial Biologics License Application for Herceptin (previously produced to Plaintiffs).
>
> INTERROGATORY NO. 6: Identify the specific range of variance approved by the FDA relating to the concentration level of Trastuzumab in the reconstituted Herceptin solution.

> ANSWER: Subject to and without waiving its General Objections, and pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, Genentech directs Plaintiffs to the Chemistry, Manufacturing and Controls section of its initial Biologics License Application for Herceptin (previously produced to Plaintiffs).

Genentech's Responses and Objections to Plaintiffs' First Set of Discovery Requests Regarding Preemption at 8 (July 13, 2016) (MDL Doc. #64-5 filed July 28, 2016). If Genentech prevails in this argument, Plaintiffs could lose claims worth millions of dollars based on a document they will never see and whose contents they will never know.

Additionally, the federal rules permit Plaintiffs to provide their subject matter expertise to assist Plaintiffs' attorneys in sorting through the scientific and regulatory documents produced. Genentech does not get to decide whether Plaintiffs' attorneys would benefit from talking to their clients. *Contra* Mot. at 7. Plaintiffs must follow the instruction Genentech placed on its prescribing information. They have experience and knowledge that attorneys do not in working with labels, prescribing information, measurements, variances, and other issues relevant to the preemption arguments and the merits of this case.

Permitting an attorneys' eyes only designation would impose a great hardship on Plaintiffs despite the fact, as shown below, the lack of such a designation would pose no tangible threat to the confidentiality of the document.

II. The Protective Order Adequately Guards Against Disclosure To Genentech's Competitors.

A. The Protective Order Guards Against Disclosure Of Trade Secrets.

The Court's Protective Order contemplates and addresses the need to protect trade secrets. First, parties may designate any material that is believed "in good faith" to "constitute, reflect or disclose trade secret or other confidential research, development or commercial information contemplated under Rule 26(c)" as Confidential Information. Protective Order § 1.b. (MDL Doc. #43) (June 24, 2016). Additionally, a party may heighten the protection for its "extremely sensitive" material by designating it as Highly Confidential:

> All documents and information described in Paragraph (1)(c) as Confidential Information and which a party, and the party's counsel, believes to be extremely sensitive confidential and/or proprietary information, the disclosure of which, even limited to the restrictions placed on Confidential Information in this Order, would compromise and/or jeopardize the Supplying Party's competitive business interests ("Highly Confidential Information"), may be designated as "Highly Confidential" by said party and furnished to the other parties pursuant to this Order.

Id. § 1.d.

Confidential Information and Highly Confidential Information may not be used for any purpose other than this litigation:

> 3. Use of Confidential Information or Highly Confidential Information
>
> Subject to Paragraph 13(c), Confidential Information or Highly Confidential Information shall not be used by any person, other than the Supplying Party, for any purpose other than conducting this Proceeding, **No. 15-CV-157-TCK-TLW**, which case is pending in the United States District Court for the Northern District of Oklahoma, and in no event shall such information be used for any business, competitive, personal, private, public or other purpose.

Id. § 3. This restriction explicitly prohibits any use for "business, competitive, personal, private, public, or other purpose. *Id.* And the Protective Order makes the "attorneys of record" responsible for "employing reasonable measures" to control access and distribution of Highly Confidential Information. *Id.* § 5.

Genentech provides no justification for why these current protections are insufficient.

B. Plaintiffs Are Not Competitors.

Genentech repeatedly expresses concern about disclosure of its trade secrets to its *competitors*—none of whom are parties to this case. The "Highly Confidential Information" category in the Protective Order is adequate to prevent Genentech's information from falling into the hands of its competitors.

Plaintiffs are not Genentech competitors—they are health care providers who use Herceptin to treat their patients. Despite this fact, Genentech contends that an attorneys' eyes only provision is necessary to prevent its competitors from obtaining information regarding its patent-protected medicine. *See* Mot. at 5 (Genentech's concern is that the information, "if disclosed, would provide competitors with insights into Genentech's strategy for developing new drugs"); *id.* at 3 (describing Case Management Conference where "Counsel for Genentech reiterated the risks posed by unlimited disclosure of its trade secrets") (emphasis added); *id.* at 5 ("Much of the information contained within the Herceptin® BLA is highly confidential, commercially sensitive, trade secret information not generally known to the public.") (emphasis added); *see also* Def.'s Obj. to Magistrate Judge's Protective Order at 4 (Doc. #90 in 15-cv-157) (Feb. 8, 2016) (Genentech's "internal documentation . . . would

be of immense interest to Genentech's competitors"); *id.* at 2 ("The documents and information that are potentially subject to discovery in this case would, if disclosed to Plaintiffs, Genentech's competitors and the public, irreparably damage Genentech's position in a highly competitive market.") (emphasis added).

Because Plaintiffs are not themselves Genentech's competitors, highly sensitive information could reach those competitors only if Plaintiffs violate the Protective Order. Genentech paints an implausible scenario in which disclosure of information in this allegedly case-dispositive document to a single client leads to "losing a decade of research and development, millions of dollars, and considerable human capital." Mot. at 10. Genentech ignores the fact that the Protective Order severely limits the use of all Confidential Information to this litigation and provides safeguards against unilateral public disclosure of the information even in the course of the litigation. With respect to "Highly Confidential Information," the Protective Order goes even further, limiting access to such materials to "Two (and no more than two) directors, officers, employees or other representatives of a party or its corporate parent designated as having responsibility for making business decisions dealing directly with the resolution of this Proceeding." Protective Order § 5.b.vi. (MDL Doc. #43) (June 24, 2016).

C. Genentech Provides No Evidence That Plaintiffs Will Violate The Current Protective Order.

Genentech's stated fears that documents designated as "Highly Confidential" will reach Genentech's competitors is based on an assumption that the very few

Plaintiff representatives with access to the information are not trustworthy and will violate the Protective Order. This Court previously rejected Genentech's argument:

> MR. O'CONNOR: ...they could take the terms of that, they could learn pricing information, and they could go to a different group purchasing organization and say, hey we now know your profit margin, we now know the supply issues.
>
> THE COURT: Right. That -- that -- I mean, that would be a violation of the order, though.... even if it weren't attorneys' eyes only or if under attorneys' eyes only there's some limited ability to share with a client it would still -- under any circumstances, that would be really a blatant violation of the protective order.

Id. at 9. The Court directly rejected Genentech's argument:

> THE COURT: Yeah, and I'm not -- I'm not going to make a decision on the assumption that somebody is going to violate the order.

Id. at 17.

When the Court asked Genentech's counsel "what incentive do [Plaintiffs] have to use it other than for purposes of the litigation?," Genentech's counsel responded:

> MR. O'CONNOR: You know, I guess the flip side of that, Your Honor, is how could they ever object to an attorneys' eyes only provision if they had no adverse motivations?

Id. at 7-8. The Court noted this non-sequitur: "...And so what I'm hearing is that the plaintiffs don't have any real incentive to use this information." *Id.* at 8.

Genentech's arguments have not changed. Nor does it have evidence that Plaintiffs' incentives have changed. Genentech just desires a third bite at the apple. This third attempt is indistinguishable from Genentech's prior failed attempts to deny Plaintiffs access to critical documents in this case and create a wall between Plaintiffs and their attorneys with respect to the information contained in those documents.

III. Genentech's Designations Are Vastly Overbroad, Including Genentech's Designation Of Many Publicly Available Documents As "Attorneys Eyes Only."

Finally, contrary to its Motion, Genentech has not been "circumspect" in its use of an attorneys' eyes only designation (that is not in the Protective Order). Mot. at 8. Genentech has marked numerous publicly available documents as "attorneys' eyes only." *See* Examples of Publicly Available Documents Genentech Designated As Attorneys' Eyes Only (Ex. 1).[3] And it has marked over 97% of all pages produced as attorneys eyes only.

Also, after filing its Motion for Protective Order, Genentech produced 3,854 more pages and designated every page as attorneys' eyes only without first asking the Court for such a designation. Genentech still has not requested the Court's permission to designate the 3,854 new pages as attorneys' eyes only. Plaintiffs ask the Court to clarify that Genentech cannot unilaterally deem documents as attorneys' eyes only under the operative Protective Order, especially as it seems Genentech intends to designate almost every page it produces as such.

CONCLUSION

So far, Genentech has designated over 97% of the pages produced as attorneys' eyes only without first obtaining the permission of the Court to use this designation

[3] At the upcoming hearing, Plaintiffs' counsel will provide hardcopy examples of some documents Genentech marked "attorneys' eyes only" and the exact document as available on the internet. Those documents are not attached here to avoid any arguable need to file under seal, even though the Protective Order permits parties to disregard confidential designations when documents are publicly available. Protective Order § 13.a. (MDL Doc. #43) (June 24, 2016).

at all. Plaintiffs ask the Court to clarify that Genentech may not unilaterally deem documents attorneys' eyes only under the operative Protective Order.

Genentech fails to show Plaintiffs' very limited access to Genentech's "Highly Confidential" documents poses any competitive threat to Genentech. The Court should deny Genentech's Motion for Protective Order.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of July, 2016, I electronically transmitted the foregoing document to the Clerk of the Court using the CM/ECF System for filing as required in the Court's Practice and Procedure Order (MDL Doc. #6 at ¶5).

/s/ David E. Keglovits
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